The FECAL trial, Fecal therapy to Eliminate Clostridium difficile Associated Longstanding diarrhoea.

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Hypothesis: An important factor in recurrence of Clostridium difficile associated diarrhoea is persistent disturbance of intestinal flora. With restoration of flora by feces from a healthy donor future recurrences can be prevented.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25892

Bron
NTR

Verkorte titel
the FECAL trial

Aandoening

1. Clostridium difficile;

2. Recurrent (NLD: recidiverend);

3. antibiotic associated diarrhoea;

4. diarrhoea (NLD: diarree);

5. feces (NLD: ontlasting);

6. transplantation (NLD: transplantatie).

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam
the Netherlands
Overige ondersteuning: ZonMW
Academic Medical Center Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Diarrhoea and Clostridium difficile toxin in stool after 10 weeks.

Toelichting onderzoek

Achtergrond van het onderzoek

Recurrent Clostridium difficile associated diarrhoea is an emerging problem in Hospitals and Nursing Homes throughout the western world. Clostridium difficile associated diarrhoea is thought to recur due to persisting spores and bacteria in the intestine on the one hand, and a long term disturbance of intestinal homeostasis on the other. Restoring the intestinal flora with feces from a healthy donor is believed to be effective in the prevention of recurrences. This trial is performed in which infusion of donor feces through a duodenal tube is compared with conventional antibiotic therapy, or antibiotic therapy with bowel lavage.

Endpoints are diarrhoea and Clostridium toxin in stool after 10 weeks (primary) and after 5 weeks, as well as inflammatory markers, cost and quality of life. Follow up is 10 weeks.

Doel van het onderzoek

Hypothesis: An important factor in recurrence of Clostridium difficile associated diarrhoea is persistent disturbance of intestinal flora. With restoration of flora by feces from a healthy donor future recurrences can be prevented.

Onderzoeksopzet

Day 1, 5, 7, 14, 21, 28, 35, 42, 49, 56, 63, 70.

Onderzoeksproduct en/of interventie

Arm 1: vancomycin 500 mg qid, 14 days;

Arm 2: vancomycin 500 mg qid, 14 days, with a bowel lavage with kleanprep on the fourth day;

Arm 3: vancomycin 500 mg qid 4 days, followed by a bowel lavage, followed by infusion of donor feces through a nasoduodenal tube on the fifth day.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patient 18 years or older;

2. proven recurrence of Clostridium difficile associated diarrhoea (positive toxin test and diarrhoea defined as more than 3 loose or watery stools per day or >8 in 48 hours);

3. In previous episodes of Clostridium difficile associated diarrhoea at least one proper course of antibiotic therapy. (at least vancomycin 125 mg qid for 10 days or metronidazole 500 mg tid for 10 days).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Pregnancy;

2. life expectancy of less than three months;

3. expected longlasting immunecompromised state (CD4<240, cytotoxic chemotherapy);

4. Prednisolon (>20 mg a day) expected to be prescibed for more than 30 days;

5. Need for continuous use of antibiotic other than for treatment of Clostridium difficile infection.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2008
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-01-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1135
NTR-old	NTR1177
Ander register	:
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A